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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	**LAZARUS Alan H. et al.**
Serial No.	:	**09/579,548**
Filed	:	**May 26, 2000**
Title	:	**USE OF A SOLUBLE RECOMBINANT HUMAN CD40L PROTEIN FOR INHIBITING AN IN VIVO ALLOIMMUNE RESPONSE**
Examiner	:	**Phillip Gambel**
Group Art Unit	:	**1644**

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DECLARATION OF ALAN H. LAZARUS

I, Alan H. Lazarus declare as follows:

1. I am co-inventor of the invention disclosed and presently claimed in the above identified patent application.

2. I am the head researcher of the Lazarus Research Group at the St. Michael's Hospital, Transfusion Medicine Research, in Toronto, Ontario, Canada.

3. I am the first author of the article entitled "Inhibition of a secondary human alloimmune response via the soluble active component of CD154 (CD40L) in severe combined immune-deficient mice engrafted with human lymphocytes" Lazarus et al, *Transfusion,* Volume 39, August 1999, pp. 818-823, wherein the humanized in

vivo animal model of the present invention was used by Lazarus et al for the examination of alloimmune response in patients.

4. I further declare that the humanized in vivo animal model of the present invention was additionally cited in the article entitled "Gamma-globulins prepared from sera of multiparous women bind anti-HLA antibodies and inhibit an established in vivo human alloimmune response" Semple J.W. et al., *Blood* 2002, August 1;100(3): 1055-9; wherein the model of the present invention was used by Semple et al for the correlation of the vivo animal model to in vivo clinical results.

5. I further declare that the humanized in vivo animal model of the present invention was additionally cited in the article entitled "Human-SCID mouse chimeric models for evaluation of anti-cancer therapies" Bankert et al, *TRENDS in Immunolgy*, Vol.22, No.7, July 2001, pp. 386-393 supports that "*data obtained from SCID mouse models correlate with observations in cancer patients; thus, the SCID mouse models might be useful for in vivo testing of new agents and methods of drug delivery*" wherein, the model of the present invention, as identified in Bankert et al as "Model Two" and has been noted as being "*a model that is more clinically relevant*" and is a model that is acceptable for correlations and evaluations to humans.

6. I declare that the animal model used in the present invention is a humanized in vivo animal model.

7. I further declare that the humanized in vivo animal model of the present invention is an immune-deficient mouse model (SCID) for the study of in vivo human alloimmune responses.

8. I declare that the humanized in vivo animal model of the present invention is an accepted model for the evaluation and correlation of in vivo animal immune responses to human patients.

9. I further declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application and any patents issuing thereon.

Date: NOV. 10, 2003

Alan H. LAZARUS